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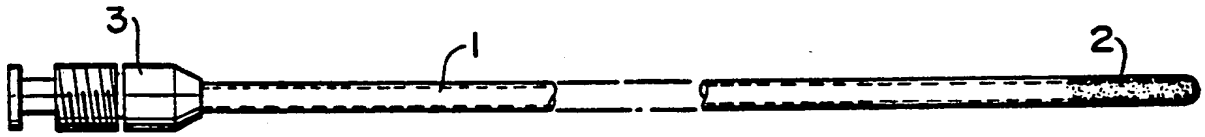
(54) Title: A CATHETER COMPRISING A POROUS TIP PORTION AND TWO PROCESSES FOR OBTAINING SUCH A CATHETER



(57) Abstract

The present invention is a catheter which is characterized by the fact that a pliable tip portion is formed at one end of a non-porous PTFE tube as an integral part of said non-porous tube, said tip portion being expanded so that the structure of said tip portion is converted into a porous structure, thus making said tip portion more pliable than the aforementioned non-porous tube. As a result of the aforementioned porous tip portion being formed at one end of the aforementioned non-porous PTFE tube, damage to the interior walls of the heart or blood vessels, etc., by the tip of the catheter is prevented.

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A catheter comprising a porous tip portion and two processes for obtaining such a catheter.

FIELD OF THE INVENTION

The present invention relates to medical catheters such as heart catheters, blood vessel shadow forming catheters, catheters which are positioned inside blood vessels, etc.

BACKGROUND OF THE INVENTION

In the case of heart catheters, catheters used to form blood vessel shadows, catheters used to measure blood flow and catheters used to extract fluids, etc., it is necessary that the tip portions (etc.) of the catheters not damage the internal walls of blood vessels. Furthermore, accurate and reliable insertion is required. Accordingly, tubes consisting of a synthetic resin such as polyethylene or polyurethane, etc., are used as such catheters. In such tubes, the tip portion of the tube consists only of the aforementioned pliable resin material. However, the other portions of the tube consist of a multi-layer tube which has a braided stainless steel wire mesh installed in the tube wall, or which has a nylon core or other high-hardness layer attached to the inside surface of the tube, in order to facilitate manipulation of the catheter during insertion. Specifically, an attempt is made to improve the accuracy and reliability of insertion (which is performed while forming a shadow by means of X-rays, etc.) by maintaining pliability in the tip portion of the catheter tube, which does not have a multi-layer structure, and by increasing the torque value in the other multi-layer portions of the catheter tube.

Even though desirable catheter characteristics may be obtained in conventional catheters such as those described above, the structure of the multi-layer portion which constitutes the greater part of each catheter is complicated, so that manufacture is not easy. As a result, such conventional catheters are unavoidably expensive.

Furthermore, the abovementioned multi-layer portion naturally requires a certain thickness. As a result, the external diameter of the catheter tube is unavoidably increased relative to the internal diameter, so that the catheter size is increased without any increase in the internal diameter.

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SUMMARY OF THE INVENTION

A catheter is described, comprising a non-porous tube of polytetrafluoroethylene (hereinafter PTFE) having integrally connected to one end a tip portion comprising a porous tube of PTFE.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of one example of the catheter of the present invention. Figures 2 through 4 are explanatory diagrams which illustrate the stages of respective methods which can be used to manufacture the non-porous tube part and the pliable tip part of the catheter of the present invention as a single integral unit.

In these figures, (1) indicates a non-porous PTFE tube, (2) indicates a pliable tubular PTFE part with a porous structure, (3) indicates a connector, (4) indicates a tubular cover, (5) indicates an intermediate tubular porous PTFE portion and (6) indicates the direction of a tensile force applied to a non-porous PTFE tube to cause it to become porous.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is a catheter which is characterized by the fact that a pliable tip portion is formed at one end of a non-porous PTFE tube as an integral part of said non-porous tube, said tip portion being expanded so that the structure of said tip portion is converted into a porous structure, thus making said tip portion more pliable than the aforementioned non-porous tube.

As a result of the aforementioned porous tip portion being formed at one end of the aforementioned non-porous PTFE tube, damage to the interior walls of the heart or blood vessels, etc., by the tip of the catheter is prevented.

Furthermore, since the intermediate portion and opposite end of the catheter consist of the aforementioned non-porous polytetrfluoroethylene tube, the catheter has desirable torque characteristics. As a result, pushing and rotary mainpulation by an operator outside the body (e.g., a physician) are facilitated and made more accurate and reliable. Accordingly, stable and appropriate catheter operation can be realized.

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Since the aforementioned non-porous tube part and the aforementioned porous pliable tip part are connected as an integral unit, said non-porous tube part and porous tip part are firmly and stably connected. Furthermore, since both parts are made of the same material, and since the internal and external diameters are more or less uniform, the overall thickness of the tube is relatively small.

Furthermore, since the entire catheter is formed from PTFE, said catheter is biologically inert.

As is shown in Figure 1, a porous PTFE part (2) is formed at the tip of a PTFE tube (1) which has a non-porous structure. A connector (3) may be attached to the non-porous end of the aforementioned tube (1).

Methods for obtaining such a catheter of the present invention are illustrated in Figures 2, 3 and 4. In the method illustrated in Figure 2, a non-porous PTFE tube (1) is manufactured by an ordinary method; afterward, an intermediate portion of said tube (2) is subjected to expansion, as taught by U.S. Patent 3,953,566. Expansion of PTFE produces a porous microstructure of nodes interconnected by fibrils. Following this formation of a porous structure by expansion, the porous portion is sintered as taught by U.S.P. 3,953,566. Next, the porous portion is cut at an intermediate point, forming the aforementioned tip part (2) as shown in Figure 2 (B). In any case, a catheter with a tip part (2) which is made pliable as a result of the aforementioned conversion to a porous structure, and which has roughly the same wall thickness as the non-porous tube (1), is obtained as a result of this procedure. The porosity of this tip part (2) is generally 30 to 95%, and preferably 60 to 90%. The mean fibril length is 0.01 to 20 microns, and preferably about 1 to 5 microns. A catheter tip made according to these parameters is hydrophobic (at atmospheric pressure and 23°C), is much more pliable than non-porous PTFE, and is not so porous as to readily allow tissue to grow into the porous microstructure.

The fibril length of expanded PTFE is determined by photographing the surface of the sample with a scanning electron microscope (SEM). The magnification level should be such that at least five complete consecutive fibrils are shown within the length of the SEM photograph. Two parallel lines are drawn 12 mm above and below the longitudinal centerline of the photograph, parallel to the direction of the

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fibrils. Following the top edge of the upper line and starting from the left margin of the photograph, the distance from the left end of the first distinct fibril nearest the drawn line to the right end of the same fibril is measured as the first fibril length. The fibril end is the point at which the fibril contacts the node. Measurements should be made using dividers referenced to a scale that accounts for the magnification factor.

Five consecutive fibril length measurements should be made in this manner along the drawn line. The photograph should be rotated 180° and five more consecutive fibril length measurements taken from the left margin of the photograph along the top edge of the second drawn line. The mean fibril length of the sample is taken to be the mean of the ten photograph measurements.

A catheter of the present invention can also be manufactured by a method exactly the opposite of that used to manufacture the catheter shown in Figure 2. In this case, a porous PTFE tube obtained by expansion is used as the base material. As is shown in Figure 3, an intermediate portion of this porous tube is covered with a cover (4) consisting of a material with a low thermal conductivity (e.g., a ceramic or similar material). In this covered state, the tube is heated to a temperature higher than the sintering temperature used for the catheter shown in Figure 2; as a result, the porous portions of the tube other than the covered portion are melted to form a non-porous tube (1). The porous intermediate portion (5) obtained as a result (as shown in Figure 3 (B)) is cut, producing a product in which said porous portion forms the aforementioned tip part (2). In this case, as in the case described above, the porosity of the tip part (2) is generally 30 to 95%, preferably 60 to 90%, and the mean pore size is 0.01 to 20 microns, preferably 1 to 5 microns.

A product of the type shown in Figure 4 (C), which has a pliable tip part (2), can be obtained by applying a tensile force (6) to one end of a non-porous tube (6) (produced previously by the extrusion molding of a PTFE paste) as shown in Figure 4 (B) immediately after said tube end has been heated, so that said end portion of the tube (1) is made porous. In this case, a product is obtained which has a pliable tip part (2) whose porosity and mean pore size (resulting from the aforementioned conversion to a porous structure) are similar to those of the catheters illustrated in Figures 2 and 3.

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It would also be possible to manufacture a catheter containing a shadow-forming agent by mixing a powdered shadow-forming agent such as barium sulfate with a fine PTFE powder, or by using a coagulation method. A non-porous PTFE tube is extruded from this mixture or coagulation, and the tip portion of this tube is subsequently heated and expanded to make the tip portion porous. In this way, a catheter could be produced which would form an appropriate shadow when exposed to X-rays, etc. For example, a desirable product may be obtained by (a) forming a tube from a mixture produced by mixing a powdered shadow-forming agent with a mean particle size of 10 microns or less (in an amount equal to 20 to 70 wt percent of the mixture) and a fine PTFE powder (in an amount equal to 30 to 80 wt percent of the mixture), and (b) converting one end portion of said tube into a porous structure by expansion, thus producing a product in which the abovementioned powdered shadow-forming agent present in the aforementioned tip part (2) is concentrated primarily in the micronodes of the fibrilized structure.

In any case, products with any desired internal diameter and external diameter can be obtained; however, products with an external diameter of 1.5 to 3 mm, an internal diameter of 1.0 to 1.8 mm and a wall thickness of approximately 0.3 to 0.6 mm are especially practical. Compared to the aforementioned conventional catheters using a braided stainless steel wire mesh, the present invention makes it possible to produce a catheter which has a smaller external diameter relative to the internal diameter. The torque value of the non-porous tube portion is approximately 3 to 7 times that of the porous tip part. Accordingly, manipulation is facilitated while damage to the internal walls of blood vessels, etc., that might be caused by the tip part (2) is prevented. The catheter can thus be accurately used to form shadows in X-ray exposures, etc., while being easily manipulated by manual pushing and rotation.

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We claim:

1. A catheter comprising a non-porous tube of polytetrafluoroethylene having integrally connected to one end a tip portion comprising a porous tube of PTFE.
2. A catheter according to claim 1 wherein said porous tube has a fibril length less than about 20 microns.
3. A catheter according to claim 1 wherein said porous tube has a fibril length less than about 10 microns.
4. A catheter according to claim 1 wherein said porous tube has a fibril length less than about 5 microns.
5. A catheter according to claims 1, 2, 3 or 4 containing a shadow-forming agent.
6. A process for obtaining a catheter having a porous tip comprising
   a) heating a tube of non-porous PTFE; and
   b) expanding a portion of said tube to make said portion porous.
7. The process of claim 6 wherein only the portion of said non-porous tube to be expanded is heated.
8. The process of claims 6 or 7 wherein said tube is sintered after heating and expanding.
9. The process of claims 6 or 7 wherein said porous portion is cut after heating and expanding.
10. The process of claims 6 or 7 wherein said tube of non-porous polytetrafluoroethylene contains a shadow-forming agent.
11. A process for obtaining a catheter having a porous tip comprising
   a) placing a heat shield over a portion of the length of a porous PTFE tube;
   b) heating the remaining portions of the length of said tube to make them substantially non-porous.
12. The process of claim 11 wherein said porous portion is cut after heating and expanding.
13. The process of claim 11 wherein said tube of non-porous polytetrafluoroethylene contains a shadow-forming agent.

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Fig. 1

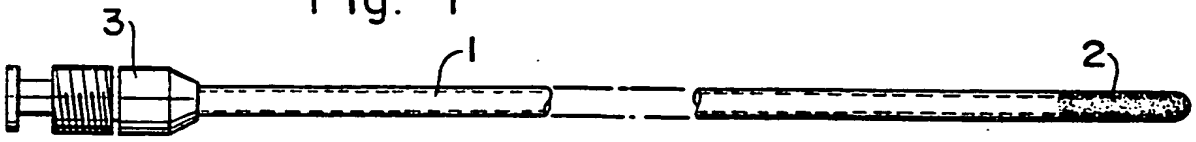

Fig. 2A

Fig. 2B

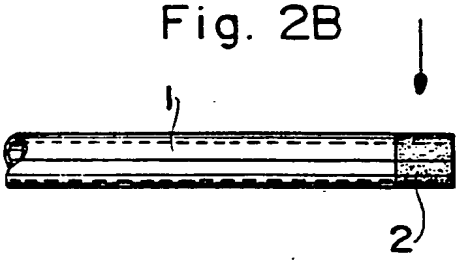

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Fig. 3A

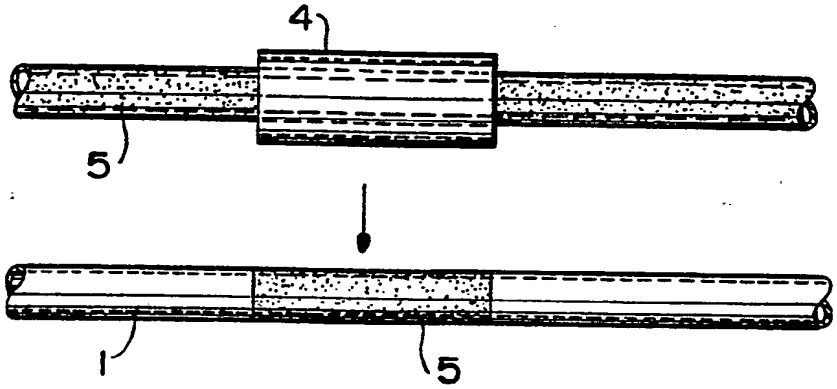


Fig. 3B

Fig. 4A

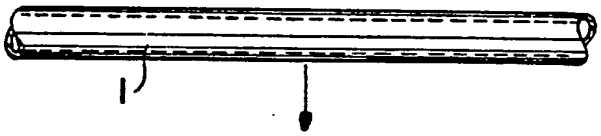


Fig. 4B

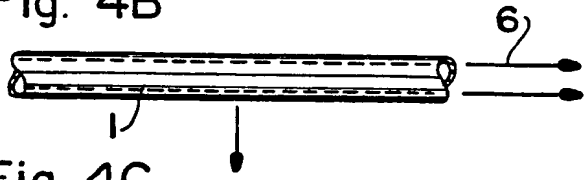
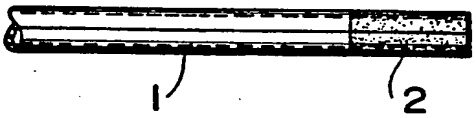


Fig. 4C



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INTERNATIONAL SEARCH REPORT

International Application No PCT/US 89/05294

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC5: A 61 M 25/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC5	A 61 M; B 29 C; B 29 D

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	US, A, 4280500 (ONO) 28 July 1981, see e.g. fig. 3 and adherent text, ex. 1, step 3, and ex. 3, last paragraph	1,5,11, 13
Y		2-4,6,8
	--	
Y	US, A, 4106509 (MCWHORTER) 15 August 1978, see e.g. claims 6-8 and corresponding parts of the description	2-4
	--	
Y	US, A, 4049589 (SAKANE) 20 September 1977, see e.g. Example 1	2-4,6,8
	--	

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
11th April 1990	23 APR 1990
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	Mme N. KUIPER

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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
Y	US, A, 3094762 (NORMAN CHARLES JECKEL) 25 June 1963, see e.g. claim 1 --	6
Y	US, A, 3953566 (GORE) 27 April 1976, see e.g. column 2 and claim 1 --	6,8
A	DE, B2, 1965487 (CHEMPLAST, INC.) 14 December 1978, see e.g. Beispiel 1-5 --	1,5

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. PCT/US 89/05294

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This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 28/02/90
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A- 4280500	28/07/81	NONE		
US-A- 4106509	15/08/78	CA-A-	1099172	14/04/81
		DE-A-	2734742	09/02/78
		FR-A-	2360319	03/03/78
		GB-A-	1525357	20/09/78
US-A- 4049589	20/09/77	AU-B-	470481	18/03/76
		AU-D-	6685074	25/09/75
		CA-A-	1033132	20/06/78
		DE-A-C-	2413221	17/10/74
		FR-A-B-	2222200	18/10/74
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		JP-A-	49118760	13/11/74
		SE-B-C-	387886	20/09/76
		JP-A-	49132156	18/12/74
		JP-A-	49118761	13/11/74
US-A- 3094762	25/06/63	NONE		
US-A- 3953566	27/04/76	BE-A-	767423	18/10/71
		CA-A-	962021	04/02/75
		CH-A-	555377	31/10/74
		DE-A-B-	2123316	02/12/71
		FR-A-	2090775	14/01/72
		GB-A-	1355373	05/06/74
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		JP-A-	51030277	15/03/76
		NL-A-	7107000	23/11/71
		SE-B-C-	392582	04/04/77
		US-A-	3962153	08/06/76
		US-A-	4187390	05/02/80
		US-A-	4096227	20/06/78
DE-B2- 1965487	14/12/78	GB-A-	1295873	08/11/72
		US-A-	3608555	28/09/71

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